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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 02/11/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/967,186

Applicant(s)

ELLIS ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 6, 7, 8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/02845 to Wink et al. in view of U.S. Patent No. 6,615,067 to Hoek et al.

In reference to claims 1, 3, 6, 7, 8, 14 and 15, Wink et al. discloses a sensor with an electrically conductive substrate having an amperometric response that is unaffected by the presence of nitric oxide; and a coating for reacting with nitric oxide or superoxide so as to cause a change in the electrochemical potential of the nitric oxide (Page 7, line 31 – Page 8, line 2). The sensor comprises a catalytic material capable of oxidizing nitric oxide (Page 11, lines 6 – 24). Wink et al. discloses the sensor for detecting and/or measuring NO (nitric oxide) in vivo (Page 12, lines 5 – 9). However, Wink et al. fails to disclose the sensor being included in an elongated wire assembly capable of being guided to a region of a vessel, the assembly having a core section including a lumen, and an opening in the core section in fluid communication with the vessel. However, Hoek et al. discloses an elongated wire assembly (Figure 7) capable of being guided to a region of a vessel, the assembly having a core section including a lumen (32), and an opening in the core section in fluid communication with the vessel. The sensor (32) is positioned within the lumen so that the sensor is in fluid communication with the vessel (Col. 7, lines 56 – 58). It would have been obvious to one having ordinary skill in the art at the time invention was made to include the sensor as disclosed by

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Wink et al. in the elongated wire assembly as taught by Hoek et al. in order to investigate a physiological parameter inside the living body with an easy-to-manufacture and easy-to-manipulate device (Col. 1, lines 62 – 65).

3. Claims 1, 2, 4, 5, 7 – 9, 11, 13, 15 and 17 - 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,582,170 to Soller in view of U.S. Patent Application Publication No. 2003/0013985 to Saadat.

In reference to claims 1, 2, 4, 5, 7 – 9, 11, 13, 15 and 17 - 19 Soller discloses an elongated assembly and a method using the elongated assembly comprising: positioning the elongated assembly into a designated region within a blood vessel (Col. 11, lines 16 – 19); measuring the level of nitric oxide (NO) in the region of the vessel (Col. 11, line 20); delivering a stimulant to increase the production of NO (Col. 11, lines 21 – 36); wherein the elongated assembly comprises a sensor having: a compound which can react with NO causing the optical properties of the compound to change; and an optical system for measuring the optical properties of the compound. Soller discloses the optical system including a first optic line for illuminating a light on the compound and a second fiber optic line to receive the light from the compound and to relay the received light to a detector (Col. 8, line 36 – 56). Soller discloses the sensor comprising a catalytic material capable of oxidizing NO (Col. 10, lines 23 – 44). However, Soller fails to disclose the elongated assembly having a core section including a lumen, having an opening in the core section in fluid communication with the vessel and being configured to allow a catheter assembly to be disposed over a portion thereof. However, Saadat discloses an elongated assembly (Figure 2) having a core section including a lumen (22), having an opening in the core section in fluid communication with the vessel and being configured to allow a catheter assembly (18) to be disposed over a portion thereof. The sensor is capable of bending away from a central longitudinal access of the core section

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[0024]. It would have been obvious to one having ordinary skill in the art at the time invention was made to include the sensor as disclosed by Wink et al. in the elongated wire assembly as taught by Saadat et al. in order to dispose the sensor in a hollow body organ and take readings at multiple locations [0010].

Claims 10, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,582,170 to Soller in view of U.S. Patent Application Publication No. 2003/0013985 to Saadat as applied to claim 8 above, and further in view of U.S. Patent No. 5,945,542 to Cooke et al.

In reference to claims 10, 12 and 16, the method as disclosed by Soller in view of Saadat as discussed above fails to disclose the steps of inserting a catheter over the wire assembly, delivering the stimulant acetylcholine, and the designated region within the vessel being affected by restenosis. Cooke et al. discloses a method wherein an infusion catheter is advanced over a guide wire to infuse acetylcholine (Col. 18, lines 35 – 38). Cooke et al. teaches that administering acetylcholine diminishes the formation of atherosclerotic plaque and restenosis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Soller in view of Saadat to include the steps of advancing a catheter over the guidewire to administer the stimulant acetylcholine to an area of restenosis in a vessel as taught by Cooke et al. in order to diminish the formation of atherosclerotic plaque and restenosis by inhibiting adhesion of monocytes and platelets, and by reducing the proliferation of vascular smooth muscle cells (Col. 18, line 63 – Col. 19, line 3).

4. Claims 1, 2, 8, 9 and 17 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0013985 to Saadat in view of U.S. Patent Application Publication No. 2002/0072680 to Schock et al.

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In regards to claims 1, 2, 8, 9 and 17 – 19, Saadat discloses a guidewire (Figure 4) for penetrating into a vessel having a core section including a lumen (222), an opening in the core section so the lumen is in fluid communication with the vessel, a fiber optic sensor (234, 238) is positioned in the lumen of the core section so the sensor is in fluid communication with the vessel, guiding the wire assembly to a designated region of the blood vessel, allowing fluids to contact the sensor and measuring a parameter using the sensor. The guidewire is configured to allow a catheter assembly (218) to be disposed over at least a portion thereof. The distal tip is capable of bending away from a central longitudinal axis of the core section [0024]. However, Saadat discloses the sensor being a temperature sensor [0036] and fails to disclose the sensor being capable of measuring the level of nitric oxide or superoxide molecules. Schock et al. discloses a catheter for penetrating into a vessel having a fiber optic sensor (22) disposed therein. Schock et al. discloses the sensor being capable of measuring a plurality of physiological variables including nitric oxide [0037]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor as disclosed by Saadat to include the capability of measuring nitric oxide, in that Schock et al. teaches that having the capability of multiple parameter measurements is a desirable configuration [0037].

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

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JMLF
February 9, 2004


MAX F HINDENBURG
SUPERVISOR
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